List of substances	Limitations
Monochlorobenzene Monochlorobenzene.	Not to exceed 500 parts per million as residual solvent in finished basic resin in paragraph (a)(1) of this section.
N-methyl-2-pyrrolidone.	Not to exceed 0.01 percent (100 parts per million) as residual solvent in finished basic resin in paragraph (a)(2) of this section.

* * * * *

Dated: May 17, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–14697 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

Food and Drug Administration

21 CFR Parts 200, 250, and 310

[Docket No. 95N–0310]

Revocation of Obsolete Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking certain regulations that are obsolete or are no longer necessary to achieve public health goals. These regulations were among those identified for revocation in a page-by-page review conducted in response to the Administration's ''Reinventing Government'' initiative, which seeks to streamline government to ease the burden on regulated industry and consumers.

EFFECTIVE DATE: July 11, 1996.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 13, 1995 (60 FR 53480), FDA published a proposed rule to revoke certain regulations. This was done in response to the President's order to all Federal agencies to conduct a page-by-page review of all their regulations and to ''eliminate or revise those that are outdated or otherwise in need of reform.'' The proposed rule contained a section-by-section analysis of all the regulations (21 CFR parts 100, 101, et al.) that FDA intended to revoke. This final rule pertains only to those regulations (21 CFR parts 200, 250, and 310) pertaining exclusively to the Center for Drug Evaluation and Research. No comments were received in response to the proposal to revoke these regulations.

II. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule, which is the revocation of certain regulations that are obsolete or are no longer necessary, is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule is the revocation of certain regulations that are obsolete or are no longer necessary, the agency is not aware of any adverse impact this final rule will have on any small entities, and the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 200

Drugs, Prescription drugs.

21 CFR Part 250

Drugs.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 200, 250, and 310 are amended as follows:

PART 200—GENERAL

1. The authority citation for 21 CFR part 200 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 508, 515, 701, 704, 705 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360e, 371, 374, 375).

2. Sections 200.100 and 200.101 are removed and the heading for subpart D is reserved.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

3. The authority citation for 21 CFR part 250 continues to read as follows:

Authority: Secs. 201, 306, 402, 502, 503, 505, 601(a), 602(a) and (c), 701, 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b)).

§ 250.104 [Removed]

4. Section 250.104 *Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act* is removed.

§ 250.203 [Removed]

5. Section 250.203 *Status of fluoridated water and foods prepared with fluoridated water* is removed.

PART 310—NEW DRUGS

6. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e); secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

§ 310.101 [Removed]

7. Section 310.101 *FD&C Red No. 4; procedure for discontinuing use in new drugs for ingestion; statement of policy* is removed.

§ 310.304 [Removed]

8. Section 310.304 *Drugs that are subjects of approved new drug applications and that require special studies, records, and reports* is removed.

Dated: June 3, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–14587 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Lambert-Kay, Div. of Carter-Wallace, Inc. The ANADA provides for oral use of pyrantel pamoate suspension for removal of large roundworms and hookworms in puppies and dogs and to prevent reinfections of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1616.

SUPPLEMENTARY INFORMATION: Lambert-Kay, Div. of Carter-Wallace, Inc., P.O. Box 1001, Half Acre Rd., Cranbury, NJ 08512–0181, filed ANADA 200–028, which provides for oral use of Evict®, Lassie®, and Vet's Own™ (pyrantel pamoate) liquid wormer for removal of large roundworms (*T. canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*) in puppies and dogs and to prevent reinfections of *T. canis* in puppies and adult dogs and in lactating bitches after whelping. The product contains pyrantel pamoate equivalent to 2.27 milligrams of pyrantel base.

Approval of ANADA 200–028 for Lambert-Kay's pyrantel pamoate suspension is as a generic copy of Pfizer's NADA 100–237 Nemex™ (pyrantel pamoate). The ANADA is approved as of March 28, 1996, and the regulations in 21 CFR 520.2043(b)(2) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.2043 is amended by revising paragraph (b)(2) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

* * * * *

(b) * * *

(2) *Sponsors.* See No. 000069 for use of 2.27 and 4.54 milligrams per milliliter product. See No. 011615 for use of 2.27 milligrams per milliliter product.

* * * * *

Dated: May 15, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96–14647 Filed 6–10–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 520, 556, and 558

Animal Drugs, Feeds, and Related Products; Fenbendazole-Containing Animal Drug and Feed Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of three supplemental new animal drug applications (NADA's) filed by Hoechst-Roussel Agri-Vet Co. The supplemental NADA's expand use of fenbendazole-containing suspension, paste, and medicated animal feed products to include use in dairy cattle of breeding age for the removal and control of gastrointestinal parasites and lungworm. They also provide for the establishment of a safe concentration and tolerance for fenbendazole residues in milk of treated dairy cattle and no requirement for discard of milk from the animals.

EFFECTIVE DATE: June 11, 1996.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Hoechst-Roussel Agri-Vet Co., Rt. 202–206 North, P.O. Box 2500, Somerville, NJ 08876–1258, is the sponsor of NADA's which cover the following fenbendazole-containing animal drug and medicated feed products: 128–620 for 10 percent suspension, 132–872 for 10 percent paste, and 137–600 for 20 percent Type A medicated article, 0.5 percent pelleted top dressing, and 35 percent free-choice mineral feed. The firm holds approvals for use of the products in beef and dairy cattle not of breeding age for the removal and control of gastrointestinal parasites and lungworm (as provided for in §§ 520.905a, 520.905c, and 558.258 (21 CFR 520.905a, 520.905c, and 558.258)). The firm has submitted supplements to the NADA's providing for expanding use of the drug products to include use in dairy cattle of breeding age for the same uses currently approved for the above-mentioned production classes.

Safe concentrations for total fenbendazole residues in edible cattle tissues, a tolerance for parent fenbendazole in cattle liver (21 CFR 556.275), and a safe withdrawal time for treated beef cattle were established based on data and information submitted with the original NADA 128–620. Based on the evaluation of data generated by additional studies submitted with these supplements, the agency is establishing a safe concentration and tolerance for fenbendazole residues in milk of treated dairy cattle. Also, based on the data, no discard of milk (zero milk withdrawal) is required and the slaughter